

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT-0417	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/019843	International filing date (<i>day/month/year</i>) 28.12.2004	Priority date (<i>day/month/year</i>) 29.12.2003
International Patent Classification (IPC) or national classification and IPC C07D401/04, 401/12, 401/14, 403/04, 405/14, 413/04, 413/14, 417/04, 417/14, A61K31/4192, 31/4245, 31/4196, 31/426		
Applicant BANYU PHARMACEUTICAL CO., LTD		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	18-20	YES
	Claims	1-17, 21-23	NO
Inventive step (IS)	Claims	18-19	YES
	Claims	1-17, 20-23	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
Document 1: WO 2003/4488 A1 (Kairon Corp.), 16 January 2003			
Document 2: JP 2000-26430 A (Taisho Pharmaceutical Co., Ltd.), 25 January 2000			
Document 3: Wolfgang K.-D. Brill, "Solid-phase synthesis of 2,6,8-trisubstituted purines" Tetrahedron Letters, 2001, Vol. 42, No. 37, Pages 6515 to 6518			
<p>(i) The invention set forth in claims 1 to 17 and 21 to 23 lacks novelty and does not involve an inventive step in the light of document 1 cited in the international search report.</p> <p>Document 1 sets forth a compound having structural formula I, and indicates that in said structural formula, R⁶ and R⁷ are substituted or unsubstituted heterocyclyl groups, heterocyclyloxy groups, aryloxy groups or the like (claim 1). Document 1 also indicates that said compounds are used in the treatment of diabetes (paragraph [0001], etc.).</p> <p>(ii) The invention set forth in claim 20 does not involve an inventive step in the light of document 1 cited in the</p>			

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international search report.

It would be easy for a person skilled in the art to conceive of combining the compounds set forth in document 1 with other therapeutic agents for diabetes to constitute a medicinal composition for treating, preventing and/or delaying the development of diabetes, and said feature does not offer a particular effect.

(iii) The invention set forth in claims 18 and 19 is not disclosed in any of the documents cited in the international search report, and is therefore novel and involves an inventive step. In particular, the compound set forth in formula (I-0), which is a 2-heteroaryl substituted benzimidazole having a 5 or 6-membered nitrogen-containing aromatic heterocycle as the A ring, is not set forth in documents 1 to 3 which are acknowledged to be the most closely related prior art documents.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Int.Cl. (IPC)

31/427, 31/433, 31/4439, 31/444, 31/4709, 31/496,
a61K31/497, 31/506, 31/5377, A61P3/04, 3/10, 9/10, 13/12,
25/00, 43/00